## IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

WYETH, Plaint v.		il Action No.: 06-222 JJI
IMPAX LABORATORIES, INC.,	)	
Defenda	nt. ) )	

# DEFENDANT'S REPLY BRIEF IN SUPPORT OF MOTION FOR THE APPOINTMENT OF A SPECIAL MASTER TO MANAGE DISCOVERY AND RESOLVE DISCOVERY DISPUTES

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#### I. INTRODUCTION

Defendant Impax Laboratories, Inc. ("Impax") files this Reply Brief in support of its Motion for the Appointment of a Special Master to Manage Discovery and Resolve Discovery Disputes.

Wyeth is using every means possible to delay resolution of this lawsuit and thereby delay Impax's FDA approval of its lower cost generic venlafaxine extended release product because every additional day that Wyeth can keep competition off the market will increase Wyeth's sales by millions of dollars. Wyeth has taken numerous unreasonable positions to prevent and delay discovery including its present opposition to the appointment of a Special Master.

Wyeth's opposition is premised on the baseless proposition that there must be "exceptional circumstances" to appoint a Special Master to referee pretrial discovery disputes. This is not the law. Exceptional circumstances are only required to appoint a Special Master to recommend findings of facts and conclusions of law at trial.

With regard to pretrial discovery masters, this Court's standing order recognizes the need for Special Masters in complex intellectual property cases. In this case, there is a particular need for a Special Master, given the numerous discovery disputes between the parties. These disputes are threatening the efficient resolution of this litigation. For example, Wyeth effectively withheld the bulk of its document production until after the October 10 deadline for the completion of contention interrogatories had passed. For months Wyeth refused to produce documents at the offices of Impax's counsel until Impax would agree to pay for the costs of Wyeth's document productions, forcing Impax to file a motion to compel on the topic. (D.I. 36 at 3). Wyeth only agreed to produce the documents pending the resolution of this dispute in a letter sent on October 16, six days after the deadline for final contention interrogatories and on the very day Impax was required to file its reply brief on this motion. This delay tactic by Wyeth has deprived Impax of the ability to review the majority of Wyeth's documents before preparing its

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final contentions. A Special Master could quickly resolve disputes such as this one without having to burden the Court.

There are numerous other disputes between the parties, all of which could be resolved quickly by a discovery master. Wyeth refuses to produce documents post-dating its document productions in the Teva litigation, presumably so that it will not incur additional discovery costs in bringing this lawsuit. Wyeth refuses to produce documents from its locations and facilities overseas, even though there are clearly relevant documents in these locations. Wyeth refuses to produce electronic documents in their native format, but will only produce them with metadata stripped away. All of these disputes are the topic of Impax's motion to compel. (D.I. 36). But there are additional disputes that Impax anticipates will ripen into further motions practices.

There is no support for Wyeth's contention that a Special Master for discovery would impede discovery, multiply discovery disputes, or increase expenses for the parties. The 2003 Amendments to Rule 53 as well as this Court's standing order recognize that the contrary is true. Wyeth's unreasonable discovery positions are *delaying* discovery and impeding this litigation, which ultimately will delay the day that Wyeth has to face generic competition for its extended release venlafaxine product. These disputes are moreover multiplying the litigation costs for Impax – a much smaller generic pharmaceutical company with fewer resources – because they are forcing numerous meet and confer letters and conferences, and resulting in expensive motion practice before the Court. A Special Master would be less expensive and would expedite discovery.

#### II. ARGUMENT

A. The exceptional circumstances required to appoint a Special Master to hold trial proceedings do not apply to this motion for the appointment of a Special Master for discovery.

The crux of Wyeth's opposition is that the appointment of a pre-trial discovery master is "the exception not the rule," and that there are no exceptional circumstances in

this case. (D.I. 62 at 6 (quoting Fed. R. Civ. P. 53 Advisory Committee Notes of 2003 Amendments ("Committee Notes"))). Wyeth is conflating the standard for the appointment of a Special Master to hold trial proceedings, which requires exceptional circumstances, with the standard for the appointment of a Special Master for pretrial proceedings such as discovery, which does not.

Rule 53 originally "focused primarily on special masters who perform trial functions." Committee Notes. Accordingly, the old rule had a provision that Special Masters could only be appointed under "exceptional circumstances." 9 Moore's Federal Practice and Procedure § 53.10(2)(b)(ii). The Rule was amended in 2003, however, to reflect the fact that "[t]he appointment of masters to participate in pretrial proceedings has developed extensively over the last two decades. . . ." Committee Notes. The new Rule is bifurcated, with separate sections for the appointment of trial masters, (Section (a)(1)(B)), and for the appointment of pretrial and post-trial masters, (Section (a)(1)(C)). The appointment of a Special Master to "hold trial proceedings and make or recommend findings of fact on issues to be decided by the court without a jury" requires "some exceptional condition." Fed. R. Civ. P. 53(a)(1)(B). The appointment of a Special Master for discovery does not. Fed. R. Civ. P. 53(a)(1)(C).

Wyeth relies on the Advisory Committee Notes for the proposition that "[e]ven though the 'exceptional circumstance' requirement was deleted from the 2003

Amendments of Rule 53, the 'core of the original Rule 53 remains, including its prescription that appointment of a master must be the exception and not the rule." (D.I. 62 at 6 (quoting Committee Notes)). This passage is referring specifically to *trial masters* who recommend findings of fact and not to discovery masters. Accordingly, the quoted passage is in a section discussing the fact that "Rule 53 continues to address *trial masters* as well." Committee Notes (emphasis added).

Wyeth's reliance on Moore's Federal Practice to impose an "exceptional circumstances" restriction on the appointment of pretrial discovery masters is also misplaced. Moore's explicitly recognizes that

Under the 2003 amendments to Rule 53, the "exceptional condition" prerequisite to the appointment of a master is continued from former Rule 53 with modifications respecting its applicability. The prerequisite applies only to some appointments of a master to hold trial proceedings and make or recommend findings of fact on issues to be decided without a jury.

9 Moore's Federal Practice § 53.10(2)(b)(ii) (emphasis added).

The only case Wyeth is able to cite to in which a court refused or reversed the appointment of a Special Master was a case involving the appointment of a *trial master*, not a pretrial discovery master. In *Stauble v. Warrob, Inc.*, 977 F.2d 690, 691 (1st Cir. 1992) (cited in D.I. 62 at 7), the court held that "referring fundamental issues of liability to a master for adjudication" violates Article III of the Constitution. Impax is not seeking such extraordinary relief here.

In short, there is no need to find "exceptional circumstances" before appointing a Special Master for the mere purpose of refereeing pretrial discovery disputes.

#### B. The appointment of a Special Master for discovery is warranted.

Admittedly, there must be some showing of need before the Court appoints a Special Master for discovery. This Court has already determined, however, that the use of Special Masters for discovery facilitates "the prompt and efficient administration of justice in intellectual property cases to, inter alia, manage discovery, conduct hearings on discovery disputes and rule on same, rule on non-dispositive pretrial motions, and facilitate settlement." Standing Order of Sept. 15, 2004 at 1 (D.I. 56, Ex. 5 at 1.)

In this case, there is a particular need for the appointment of a Special Master for discovery due to the numerous discovery disputes between the parties, as detailed in Impax's opening brief. (D.I. 55 at 3-4.) The inability of the parties to resolve these disputes informally is threatening the efficient resolution of this case.

For example, although the October 10 deadline for the completion of document production has now passed, the parties continue to dispute whether Impax should be required to pay for the costs of Wyeth's document productions. (D.I. 36 at 3). Wyeth has now used this dispute to delay the majority of its document production until after the October 10 deadline for completion of contention interrogatories. Although Impax produced to Wyeth over 214,000 pages of documents at Impax's own cost and delivered those documents directly to the offices of Wyeth's counsel, at the October 10 deadline. Wyeth had not delivered a single document to Impax other than a portion of its New Drug Application and selected deposition transcripts from the Teva Litigation. Prior to the October 10 deadline, Wyeth was holding its documents hostage in Reston, Virginia until Impax agreed to pay for Wyeth's discovery obligations. (D.I. 63, Ex. 2). Only today, on October 16, six days after Impax had to finalize its contentions, did Wyeth agree to produce its documents to Impax. Reply Declaration of Mary B. Matterer in Support of Impax's Motion for the Appointment of a Special Master, Ex. 1 at 2. Regardless of how the Court resolves the issue of whether Impax must pay for Wyeth's discovery obligations, the uncertainty surrounding this dispute has resulted in Impax having to prepare its final contentions without the benefit of the majority of Wyeth's document production. The issue could have been resolved long ago by a Special Master with little expense or delay and without the need for a motion before the Court. As it stands, Impax finds itself in the position of having been sued by a much larger, branded pharmaceutical company and having its hands tied behind its back by a demand that Impax pay for the documents it needs to discover to defend the lawsuit.

There are numerous other disputes pending between the parties, all of which are impeding the progress of this litigation, some of which are the subject of pending motions to compel, some of which may soon become the subject of motions to compel. (D.I. 55 at 3-4). There is no authority for Wyeth's proposition that Impax may only rely on discovery disputes that are the subject of pending motions to establish the need for a

discovery master. (D.I. 62 at 5.) Nor is there any logic behind this position. The fact that the parties continue to have discovery disputes favors the appointment of a Special Master whether or not the parties have yet to file formal motions on all of the disputes. It is the very avoidance of future motions to compel that a Special Master would facilitate, so the Court should consider the fact that there are many disagreements between the parties that may ripen into motions practice in the near future. Wyeth suggests that the resolution of these additional disputes "could further be resolved in a conference or two with the Court." (D.I. 62 at 5.) There is no status conference scheduled until February 7, 2007. It is respectfully submitted that these discovery disputes must be resolved well before February for the litigation to proceed efficiently. In any event, the appointment of a Special Master would relieve the Court from the burden of holding such conferences to resolve these disputes.

# C. The appointment of a Special Master for discovery will not delay discovery.

Wyeth argues that a Special Master will delay discovery because "the Court would be in the position of reviewing 'de novo all objections' to the Master's Report."

(D.I. 62 at 6 (citing Fed. R. Civ. P. 53(g)(3))). Rule 53(g)(3) only requires de novo review for "objections to findings of fact made or recommended by a master." Fed. R. Civ. P. 53(g)(3). The Rule separately provides that procedural matters are subject to the abuse of discretion standard of review, unless the order of appointment establishes a different standard. Fed. R. Civ. P. 53(g)(5). "The default abuse of discretion standard of review is applicable to determinations the master makes in the course of performing his or her duties that, if made by the trial judge, would be treated as matters of procedural discretion." 9 Moore's Federal Practice § 53.42(3). Accordingly, the Special Master's management of the discovery process, including such rulings as whether documents should be produced in response to particular document requests or the required format for

document production, need only be reviewed for abuse of discretion, and not *de novo*, as Wyeth contends.

Wyeth contends that the appointment of a Special Master will multiply discovery disputes and increase expenses. The fact that the parties must pay for the services of a Special Master is commonly recognized as *discouraging* discovery disputes. For example, in a case Wyeth cites, the Seventh Circuit recommended the appointment of a discovery master "to expedite further discovery" and observed that "[t]he costs of using this procedure will fall upon the parties and possibly serve as a deterrent to further abuse." *Eggleston v. Chicago Journeymen Plumbers' Local Union No. 130*, 657 F.2d 890, 904 (7th Cir. 1981) (D.I. 62 at 8). Moreover, the quick resolution of disputes before a Special Master is far less expensive than formal motions practice, and as a much smaller, generic pharmaceutical company, Impax has a far greater interest than Wyeth in keeping costs down in this litigation. A Special Master will advance that interest.

Wyeth contends that in the cases Impax relies upon in which the court approved the appointment of a Special Master, "an inordinate extension of the proceedings and costs resulted because of objections to, appeals of, or a party's failure to comply with, the special master's order or recommendation." (D.I. 62 at 8 (citing *Aird v. Ford Motor Co.*, 86 F.3d 216, 225 (D.C. Cir. 1996); *Trans World Airlines, Inc. v. Hughes*, 332 F.2d 602, 612 (2d Cir. 1964); *First Iowa Hydro Elec. Coop. v. Iowa-Illinois Gas &Elec. Co.*, 245 F.2d 613, 618-19 (8th Cir. 1957))). In fact, none of these cases find that the appointment of the Special Master created delay or inefficiencies.

In *Aird*, the court held that the district court did not abuse its discretion in taxing the Special Master's costs to plaintiff's counsel, but nowhere stated that the appointment of the Special Master created inefficiencies. In fact, the Special Master resolved numerous discovery disputes in that case that would otherwise have been visited upon the district court. 86 F.3d at 218-19.

In *Trans World Airlines*, the Special Master navigated a similarly imposing maze of discovery disputes for the district court, and the Second Circuit nowhere stated that this led to judicial inefficiencies. 332 F.2d at 611-12.

The holding of *First Iowa* is that "[t]he court was legally empowered to appoint a master to carry out the functions actually performed by the master in this case," and the court made no statement that the Special Master led to judicial efficiencies. 245 F.2d at 628.

Wyeth offers no other support for its assertion that the appointment of a discovery master will delay discovery. This Court's standing order specifically recognizes that the contrary is true – that the appointment of a discovery master can achieve "the prompt and efficient administration of justice in intellectual property cases." (D.I. 56, Ex. 5 at 1.) Wyeth's real interest is to delay this litigation, so as to put off for as long as possible the day when it will face generic competition for its extended release venlafaxine product.

#### III. CONCLUSION

For the foregoing reasons, Impax respectfully requests that the Court appoint a Special Master in this case to manage discovery and to resolve discovery disputes.

Dated: October 16, 2006

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#### **CERTIFICATE OF SERVICE**

I hereby certify that on the 16<sup>th</sup> day of October, 2006, I electronically filed the foregoing document, **DEFENDANT'S REPLY BRIEF IN SUPPORT OF ITS MOTION FOR THE APPOINTMENT OF A SPECIAL MASTER TO MANAGE DISCOVERY AND RESOLVE DISCOVERY DISPUTES**, with the Clerk of the Court using CM/ECF which will send notification of such filing to the following:

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Additionally, I hereby certify that on the 16<sup>th</sup> day of October, 2006, the foregoing document was served via email and hand delivery on the above counsel and also via email and federal express (on 10/17/2006) on the following non-registered participants:

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